

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellants: Dekkers, et al.)
Serial No.: 10/797,975) Group Art Unit: 1713
Filed: March 11, 2004)
For: BIOCIDAL COMPOSITIONS)
AND METHODS OF MAKING)
THEREOF)

VIA ELECTRONIC FILING1

Assistant Commissioner for Patents
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REPLY BRIEF

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is The General Electric Company.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to Appellants, Appellants' legal representatives, or assignee that will directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF THE CLAIMS

Claims 1-20 are pending in the application. Claims 1-19 stand finally rejected, Claim 20 stands withdrawn, and no claims are allowed. Claims 1-19, as they currently stand, are set forth in Appendix A. Appellants hereby appeal the final rejection of Claims 1-19.

IV. STATUS OF THE AMENDMENTS

No amendments have been filed subsequent to the final rejection dated April 26, 2006. All prior amendments have been entered.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 is directed to a method of making a shaped article, comprising thermoforming an article (page 5, line 14 to line 30) comprising an exterior surface comprising an inorganic biocidal agent (page 6, line 25 to page 7, line 3) and a first thermoplastic resin (page 12, line 6 to page 13, line 13) to form the shaped article (page 31, line 19 to line 24), wherein the shaped article has improved biocidal activity (page 2, line 19 to line 24) compared to the unshaped article (page 33, line 16 to line 19).

Appellants have discovered that, unexpectedly, an article that is thermoformed to form a shaped article has superior biocidal activity over an article that is not thermoformed. As shown in Example 1 and Table 1 of the present application, thermoforming a biocidal article improves the silver release and thus the biocidal activity of the article. (page 32, line 25 to page 33, line 12) The middle and side of the thermoformed article had a silver release of 24 and 20 ppb, respectively, which is about

3-fold greater than the article that was not thermoformed, which had a silver release of 7.4 ppb.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1 – 19 stand rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over U.S. Patent No. 4,775,585 to Hagiwara, et al. (“Hagiwara”) in view of U.S. Patent No. 5,939,153 to Valyi (“Valyi”), and further in view of U.S. Patent No. 5,064,599 to Ando, et al. (“Ando”).

VII. ARGUMENT

Claims 1-19 are Non-Obvious over Hagiwara in view of Valyi and further in view of Ando.

The present invention relates to thermoforming an article comprising a thermoplastic resin and an inorganic biocidal agent. (page 2, ll. 6-9) Appellants’ have unexpectedly discovered that thermoformed articles exhibit superior inorganic biocidal agent release properties over unshaped articles.

The Examiner has combined three references to provide all elements of the Appellants’ claimed invention. Hagiwara is directed to a polymer article containing zeolite particles. (See Abstract) Valyi is directed to lined beverage containers.

Ando is directed to conjugated fibers comprising a low-melting point component and a high-melting point component, wherein the low-melting point component comprises zeolite particles. (See Abstract)

For an obviousness rejection to be proper, the Examiner must meet the burden of establishing a *prima facie* case of obviousness, i.e., that all elements of the invention are disclosed in the prior art; that the prior art relied upon, coupled with knowledge generally available in the art at the time of the invention, contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or combined references; and that the proposed modification of the prior art had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); *In Re Wilson*, 165

U.S.P.Q. 494, 496 (C.C.P.A. 1970); *Amgen v. Chugai Pharmaceuticals Co.*, 927

U.S.P.Q.2d, 1016, 1023 (Fed. Cir. 1996).

The Federal Circuit has recently held

[T]o establish a *prima facie* case of obviousness based on a combination of elements disclosed in the prior art, the Board must articulate the basis on which it concludes that it would have been obvious to make the claimed invention. In practice, this requires that the Board explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious.

In re Kahn, 441 F.3d 977, 986, 78 U.S.P.Q.2d 1329 (Fed. Cir. 2006) (internal citations and quotation marks omitted). Similarly, in *In re Oetiker*, the Federal Circuit held that “the combination of elements from non-analogous sources, in a manner that reconstructs the applicant’s invention only with the benefit of hindsight, is insufficient to present a *prima facie* case of obviousness.” *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992).

Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness. Appellants maintain that one of ordinary skill in the art would not be motivated to combine the references in the manner proposed by the Examiner. Appellants further submit that the Examiner has improperly used hindsight gleaned from Appellants’ own disclosure to piece together elements from non-analogous sources to arrive at Appellants’ invention.

In the Examiner’s Answer, the Examiner admits that Hagiwara et al. does not “literally indicate that thermoforming is involved in the molding process for containers.” (Examiner’s Answer dated December 7, 2006 at page 5) The Examiner goes on to state “the examiner has a reasonable basis to believe that both the recited “thermoforming” of claim 1 and “molding” of Hagiwara et al. (col. 9, line 49-54) embrace the same teachings.” *Id.* Appellants respectfully submit that the Examiner has vastly oversimplified the art of molding of plastic articles.

Molding is a general term that embraces generally shaping an article from a raw material by using a mold. Molding techniques suitable for use for plastics include, for example, injection molding, compression molding, transfer molding, extrusion molding, blow molding, rotational molding, laminating and thermoforming. One specific type of molding exemplified in Hagiwara is molding to form a fibrous shape. (Hagiwara et al., col. 4, ll. 59-60) Another specific molding technique taught in Hagiwara et al. is

injection molding. (Hagiwara et al. col. 16, ll. 1-3) Hagiwara et al. certainly does not specify thermoforming. Hagiwara et al. does not disclose any advantage of one form of molding over another and thus, based on the teachings of Hagiwara et al., one of skill in the art would not choose one form of molding as advantageous over another.

Further, thermoforming is a specialized type of molding in which a sheet or film is heated to its forming temperature and then stretched over a mold to produce the thermoformed article. There is no teaching in Hagiwara et al. that thermoforming is a suitable molding method for the compositions disclosed therein. Thus, there is no teaching in Hagiwara et al. that would lead one to particularly choose thermoforming over other types of molding.

For a specific teaching of thermoforming, the Examiner relies on Valyi. The Examiner has repeated the argument that the motivation to combine the teachings of Hagiwara et al. and Valyi “is that Hagiwara et al. (col. 9, line 49-54) clearly disclose that the disclosed process is suitable for making containers.” (Examiner’s Answer dated December 7, 2006 at page 6) Hagiwara teaches polymers containing zeolites, but fails to teach thermoforming to improve biocidal metal release. In order to find a reference for thermoforming, the Examiner combines the brief reference in Hagiwara to a container with a portion of Valyi, which is directed to a gas barrier liner for the inside wall of a beverage container. Appellants submit that one of ordinary skill in the art would not be motivated to combine a reference primarily directed to biocidal fibrous articles with a reference directed to a beverage container, and that there is no expectation of success for the use of the thermosetting technique of Valyi in the compositions of Hagiwara.

The Examiner has stated that “typical molding techniques for making containers...are injection molding and thermoforming techniques.” (Examiner’s Answer at page 7) The Examiner has further stated that “It would not be difficult for one of ordinary skill in the art to recognize the value of using thermoforming for making containers after reading the molding teachings of Hagiwara et al. or the continuous process for making container teachings in the disclosure of Valyi.” *Id.* Appellants respectfully submit that a conclusory statement that “it would not be difficult” does not meet the appropriate standard for obviousness. Hagiwara et al. teaches injection molding (Col. 16, ll. 1-3), but not thermoforming. Why would one of skill in the art discard the

teaching of injection molding in Hagiwara et al. in favor of thermoforming? Valyi teaches that both thermoforming and blow-molding yield similar results and either process can be used to shape an article depending on whether the original form is a sheet for thermoforming or a tube for blow-molding. (Valyi, Col. 4, ll. 6-8) Therefore, upon reading Valyi, one of ordinary skill in the art would not be compelled to select thermoforming as compared to blow molding, for example. Neither Hagiwara et al. or Valyi would compel one of skill in the art to particularly choose thermoforming over the other available molding techniques. While the Examiner appears to be equating all molding techniques, those of skill in the polymer arts are well aware that, for particular applications, one molding technique can have distinct advantages over another. Only the Appellants have discovered the particular advantage of thermoforming in improving biocidal metal release.

While one might try thermoforming an article such as that disclosed in Hagiwara et al., this is not the standard for patentability. A finding of "obvious to try" does not provide the proper showing for an obviousness determination. The requirement for a determination of obviousness is that "both the suggestion and the expectation of success" must be founded in the prior art, not in Appellant's disclosure" (emphasis added). *In re Dow Chem.*, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). An Examiner, then, cannot base a determination of obviousness on what the skilled person in the art might try or find obvious to try. Rather, the proper test requires determining what the prior art would have led the skilled person to do. While one might try thermoforming a zeolite-containing composition of Hagiwara et al. there is no expectation of success that such an article would have the desired antimicrobial properties.

It further appears that the Examiner has made an inherency argument; however, the Examiner has applied the inherency argument to Appellants' own invention rather than to the prior art. In order to support a rejection based on inherency, an Examiner must provide factual and technical grounds establishing that the inherent feature necessarily flows from the teachings of the prior art. See *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Int. 1990). In addition, the theory of inherency is normally reserved for rejections under 35 U.S.C. § 102. *In re Grasseli*, 318 U.S.P.Q. 303 (Fed. Cir. 1983).

The Examiner first refers to the heating of the low-melting component in Ando et al., but then state that “it would not be difficult for one of ordinary skill in the art to recognize that when more zeolites are exposed after thermoforming, the biocidal activities of the thermoformed object would be increased from its encapsulated form.”
(Examiner’s Answer at page 7)

The present claims require thermoforming, not simply heating:

Thermoforming comprises simultaneously heating and forming the article or multi-layer article, e.g., an extruded sheet, into the desired shape such as in a mold. Either vacuum or pressure against the mold may be used to form the article or multi-layer article.

(Specification, page 31, ll. 21-24)

Ando et al. does not teach thermoforming of articles containing zeolites. Ando et al. teaches that fibrous compositions with a low-melting point component and a high-melting point component, wherein upon heating, the low melting point component of the resins spreads to cause more zeolite particles to be exposed on the surface. Example 1 of Ando et al. disclose heating the fibrous article containing a low-melting point component and a high-melting point component at 150° C for one minute using an oven with a hot air circulation to melt the low-melting component. As one of ordinary skill in the art would understand, convection heating, such as in a recirculating hot air oven, is a relatively slow method of heat transfer. Therefore the 1 to 2 minute heating regime disclosed by Ando et al. would be insufficient to heat the core to a thermoforming temperature for the low-melting point component, let alone the high melting point component. Ando et al. therefore fails to teach or suggest thermoforming and thus cannot teach the advantages of thermoforming as disclosed in the present application compared to the simple heating disclosed in Ando et al.. It is unclear how improved properties provided by thermoforming can be inherent in an article that is not thermoformed but instead merely heated.

Thus, Ando et al. cannot inherently disclose the properties obtained through thermoforming an article.

Finally, in response to Appellants' argument that one of skill in the art would not employ the multilayer film of Valyi in the thermoplastic compositions of Hagiwara et al., the Examiner has stated:

the polyepoxide layer of Valyi is merely a barrier coating, the structural layer of the multilayer film is a polyester thermoplastic polymer...not polyepoxides. Therefore, the polyepoxide coating does not prevent or deter the polyester thermoplastic of Valyi from being used to thermoform bottles.

(Examiner's Answer at page 8). Appellants respectfully submit that the Examiner has oversimplified Valyi. Valyi is directed to a method that allows the deformation of a multilayer liner material having a barrier layer into a final shape.

To obtain said shape, the original form of the liners, be it a sheet for thermoforming, or a tube for blow-molding it, must be deformed. Once inside the preform, it is further severely deformed in the course of blow molding or stretch-blow molding the lined preform into a finished container shape. Accordingly, the liner materials, including the barrier layer encased within its layers, should exhibit sufficient ductility to render possible such deformation. The materials for lined containers according to the above cited patents are chosen accordingly, and thus limited. The polyepoxides, in their finished, i.e., cured state, are unable to undergo severe deformation, as in a total stretch ratio of 1:20, or more, from flat sheet to blown shape, as is typical for a bottle.

(Valyi, Col. 4, ll. 5-17) Valyi further discloses

[I]n order to offset the elimination of the effective barrier surface that will be present in the finished container, the polyepoxide layer that is originally deposited must be made thick enough in the same ratio as the effective surface is diminished, thereby offsetting the presence of the discontinuities referred to above.

(Valyi, Col. 4, ll. 5-17) Valyi, therefore, is expressly directed to deforming a multilayer article that comprises a barrier layer that is unable to undergo severe deformation on a structural layer comprising, for example, polyethylene terephthalate. Thermoforming and blow molding are particularly useful techniques for the formation of these multilayer articles. (Valyi, Col. 5, ll. 15-23) Thus, it is the unique multilayer structure of Valyi that compels the selection of thermoforming and blow molding techniques. Hagiwara et al. does not disclose such a multilayer structure and there is no motivation provided by these references to use such a multilayer structure in the compositions of Hagiwara et al. Thus, absent the constraints of the multilayer material of Valyi, there is no reason at all to employ thermoforming to the materials disclosed in Hagiwara et al. One of skill in the art

would apply neither the multilayer film of Valyi or the techniques used to produce it in the compositions of Hagiwara et al.

Finally, Appellants respectfully submit that the Examiner's selection of isolated teachings from the prior art reference is evidence that the Examiner has used Appellants' own disclosure as a template to piece together the teachings of the prior art. "It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *In re Fritch* 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992). Appellants maintain that the Examiner has used an improper standard in arriving at the rejection of the above claims under section 103, based on improper hindsight, which fails to consider the totality of Appellants' invention and to the totality of the cited references. More specifically, the Examiner has assembled elements from disparate references with motivation gleaned only from hindsight from Appellants' own disclosure to allegedly arrive at Appellants' invention. In doing so, the Examiner has failed to consider the teachings of the references or Appellants' invention as a whole in contravention of section 103, including the disclosures of the references, which teach away from Appellants' invention.

In order to make the combination proposed by the Examiner, one would have to focus on Hagiwara's passing reference to a container, ignore the list of useful polymers in Hagiwara, look to Valyi, which discloses various methods to manufacture containers having multilayer films comprising barrier layers from completely different polymers, ignore the barrier layers, and select only the teaching of thermoforming from Valyi to apply to the polymers of Hagiwara. There is no teaching in Valyi that thermoforming can or should be applied to the polymers of Hagiwara, let alone polymers containing zeolites. Further, one would have to combine Ando for motivation, ignoring the specific teaching in Ando directed to combinations of low-melting point and high-melting point polymers, and generalize their teaching to heating of any zeolite-containing polymers. Ando does not teach thermoforming. One of skill in the art would not be motivated to make the combination suggested by the Examiner, and there certainly would be no expectation of success for the combination. Appellants respectfully submit that Examiner has used

Appellants' own disclosure as an instruction manual to piece together selected elements from the teachings of the prior art.

For at least these reasons, the combined prior art teachings fail to provide a reasonable expectation of success by combining the references in the manner suggested by the Examiner. At best, this is only an "obvious to try" standard, which is not the proper standard for determining obviousness.

Further, the Examiner has again failed to consider the unexpected results achieved by the Appellants' invention. The Examiner has not commented on the specific improvements in biocidal metal release reported in the Appellants' Specification. Even where a *prima facie* case of obviousness exists, obviousness may be rebutted by a showing of "unexpected results," i.e., comparative test data showing that the claimed invention possesses unexpectedly improved properties, or properties that the prior art does not have. *In re Dillon*, 919 F.2d 688, 692-93, 16 U.S.P.Q.2d 1897, 1901 (Fed. Cir. 1990). The MPEP provides that objective evidence or secondary considerations such as unexpected results are relevant to the issue of obviousness and must be considered in every case in which they are present. MPEP § 2141(III). Examiners must consider comparative data in the specification, which is intended to illustrate the claimed invention in reaching a conclusion with regard to the obviousness of the claims. *In re Margolis*, 785 F.2d 1029, 228 USPQ 940 (Fed. Cir. 1986); MPEP § 716.01(a). Evidence of unexpected properties may be in the form of a direct or indirect comparison of the claimed invention with the closest prior art, which is commensurate in scope with the claims. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980); MPEP § 716.02(b) - § 716.02(e).

As shown in Example 1 and Table 1, thermoforming results in a shaped biocidal article with about a 3-fold improvement in biocidal metal (e.g., silver) ion release in the middle and sides of the article over a biocidal article which is not thermoformed. (Specification, page 33, ll. 5-12) The thermoformed article provides improved biocidal metal ion release and therefore improved biocidal activity. The biocidal activity is evidenced specifically in Table 3 where the biocidal efficacy improved dramatically with the amount of silver release. (Specification, page 35, ll. 1-5) The Examiner does not dispute the fact that the shaped article has improved biocidal activity compared to the

unshaped article. Appellants respectfully submit that the Examiner has failed to apply the *Graham* factors in the obviousness inquiry as required and failed to weigh objective evidence of nonobviousness. Specifically, Appellants respectfully submit that the Examiner has failed to consider the comparative data in the specification that demonstrate the unexpected results obtained by the present composition. These unexpected results also demonstrate that thermoforming, rather than just heating, improves the biocidal activity of the article. If heating alone were sufficient, the edges of the thermoformed article of the Appellants' Examples would have similar increases in metal release to the middle and sides. Appellants respectfully submit that the unexpected results disclosed in Example 1 would successfully rebut a *prima facie* case of obviousness, if it existed.

In summary, Claims 1-19 are non-obvious over the art of record. For the reasons cited above, Appellants respectfully submit that all of the claims are allowable and the application is in condition for allowance. Appellants respectfully request reversal of the outstanding rejections and allowance of this application.

In the event the Examiner has any queries regarding the submitted arguments, the undersigned respectfully requests the courtesy of a telephone conference to discuss any matters in need of attention.

If there are any additional charges with respect to this Reply Brief, please charge them to Deposit Account No. 50-3621.

Respectfully submitted,

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VIII. CLAIMS APPENDIX

1. (Original) A method of making a shaped article, comprising:

thermoforming an article comprising an exterior surface comprising an inorganic biocidal agent and a first thermoplastic resin to form the shaped article, wherein the shaped article has improved biocidal activity compared to the unshaped article.

2. (Original) The method of Claim 1, wherein the first thermoplastic resin comprises a homopolymer or a copolymer of a polycarbonate, a polyester, a polyacrylate, a polyamide, a polyetherimide, polyphenylene ether, or a combination comprising one or more of the foregoing resins.

3. (Original) The method of Claim 1, wherein the shaped article has biocidal activity effective to kill at least 50% of a pathogenic organism in contact with the exterior surface over a period of 24 hours at 25°C.

4. (Original) The method of Claim 1, wherein the article has a biocidal metal release factor of greater than 2.5 from an exterior surface

wherein biocidal metal release in parts per billion is measured by contacting 5 cm by 5 cm of the exterior surface with 40 milliliters of 0.8% weight/volume of sodium nitrate for 24 hours at 25° C to form a test solution, and measuring an amount of biocidal metal in the test solution in parts per billion, and

wherein the biocidal metal release factor is the amount of biocidal metal in the test solution in parts per billion divided by a product of a weight percent of the inorganic biocidal agent based on the total weight of the article and the weight percent of biocidal metal in the inorganic biocidal agent.

5. (Original) The method of Claim 4, wherein the biocidal metal release factor is greater than or equal to about 3.

6. (Original) The method of Claim 4, wherein the biocidal metal release factor is greater than or equal to about 4.

7. (Original) The method of Claim 1, wherein the exterior surface is in the form of a layer disposed on at least a portion of the article.

8. (Original) The method of Claim 7, wherein at least a portion of the shaped article comprises a second thermoplastic resin that is the same as or different than the first thermoplastic resin.

9. (Original) The method of Claim 8, wherein at least a portion of the article comprises an inorganic biocidal agent that is the same as or different than the inorganic biocidal agent in the exterior surface.

10. (Previously Presented) The method of Claim 3, wherein the biocidal activity is an anti-microbial efficacy that is greater than or equal to about 70% killing of an E. coli culture or a Staphylococcus aureus culture, measured by contacting the exterior textured surface of the article with the E. coli culture or the Staphylococcus aureus culture, incubating the article for 24 hours at 37°C, and determining the percentage of killing of the E. coli culture or the Staphylococcus aureus culture.

11. (Original) The method of Claim 10, wherein the anti-microbial efficacy of the shaped article is greater than or equal to about 95%.

12. (Original) The method of Claim 1, wherein the inorganic biocidal agent comprises a biocidal metal comprising silver, gold, copper, zinc, mercury, tin, lead, bismuth, cadmium, chromium, thallium, or a combination comprising one or more of the foregoing biocidal metals.

13. (Original) The method of Claim 12, wherein the inorganic biocidal agent is in the form of a metal salt, a hydroxyapatite, a zirconium phosphate, or a zeolite comprising at least one of the biocidal metals, or a combination comprising one or more of the foregoing forms.

14. (Original) The method of Claim 13, wherein the inorganic biocidal agent is a biocidal zeolite.

15. (Original) The method of Claim 14, wherein the biocidal zeolite comprises silver.

16. (Original) The method of Claim 2, wherein the first thermoplastic resin comprises a polycarbonate resin.

17. (Original) The method of Claim 1, wherein the inorganic biocidal agent is present at a concentration of about 0.1 wt% to about 20 wt% based on the total weight of the exterior surface.

18. (Original) The method of Claim 6, wherein the exterior surface layer has a thickness of about 5 micrometers to about 50 micrometers.

19. (Original) The method of Claim 1, wherein the shaped article reduces the growth of a pathogenic organism comprising *Bacillus cereus*, *Escherchia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Streptococcus feacalis*, *Salmonella gallinarum*, *Vibrio parahaemdyticus*, *Candida albicans*, *Streptococcus mutans*, *Legionella pneumophila*, *Fuso bacterium*, *Aspergillus niger*, *Aureobasidium pullulans*, *Cheatomium globosum*, *Gliocladium virens*, *Pencillum funiculosum*, *Saccharomyces cerevisiae*, a *Herpes simplex virus*, a *polio virus*, a *hepatitis B virus*, a *hepatitis C virus*, an *influenza virus*, a *sendai virus*, a *sindbis virus*, a *vaccinia virus*, a *severe acute respiratory syndrome virus*, or a combination comprising one or more of the foregoing organisms.

IX. EVIDENCE APPENDIX

There is no evidence submitted pursuant to 37 C.F.R. §1.130, 37 C.F.R. §1.131, or 37 C.F.R. §1.132 or any other evidence entered by the Examiner and relied upon by the Appellant in this appeal, known to the Appellants, Appellants' legal representatives, or assignee.

X. RELATED PROCEEDING APPENDIX

There are no other related appeals or interferences known to Appellants, Appellants' legal representatives, or assignee that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.